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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91194218
Party	Defendant Meridian Bioscience, Inc.
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL APPEAL BOARD

ILLUMINA, INC.,	)	Opposition No. 91194218 (parent)
	)	Ser. No. 77/768176
Opposer/Petitioner,	)	
	)	Opposition No. 91194219
-v-	)	Ser. No. 77/775316
	)	
MERIDIAN BIOSCIENCE, INC.,	)	Cancellation No. 92053479
	)	Reg. No. 3887164
Applicant/Registrant.	)	
	)	Cancellation No. 92053482
	)	Reg. No. 3868081
	)	

BRIEF OF APPLICANT / REGISTRANT MERIDIAN BIOSCIENCE, INC.

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MISCELLANEOUS

Meridian Bioscience, Inc. ("Meridian") submits this brief in opposition to Illumina, Inc.'s ("Opposer's") Petition to Cancel Registration Nos. 3868081 and 3887164 and its Opposition to registration of Serial Nos. 77/768176 and 77/775316.

DESCRIPTION OF THE EVIDENTIARY RECORD

Pursuant to 37 CFR § 2.128(b), the record consists of the pleadings, the file histories of Meridian's applications and registrations, and the file histories of Opposer's pleaded registrations for its ILLUMINA and ILLUMINADX marks. In addition, the record consists of the following evidence of Meridian: (a) testimony declarations of Vecheslav A. Elagin and Kenneth J. Kozak, with exhibits, TTABVUE #s 79 and 80; (b) cross examination transcripts of Naomi O'Grady and Karen Possemato, with exhibits, TTABVUE #s 83 and 85; (c) Notice of Reliance and supporting exhibits, TTABVUE #76; (d) rebuttal cross examination transcript of Naomi O'Grady, with exhibits, TTABVUE #97; (e) rebuttal cross examination transcript of Steven A. Young, TTABVUE #96[1]; and (f) Rebuttal Notice of Reliance and supporting exhibits, TTABVUE #100. In addition, the record consists of the following evidence of Opposer: (a) testimony declarations of Naomi O'Grady, Gregory Heath, Karen Possemato, and William Morrison, with exhibits, TTABVUE #s 60, 64, 66, and 68; (b) cross examination transcripts of Kenneth J. Kozak and Vecheslav A. Elagin, with exhibits, TTABVUE #s 86 and 88; (c) Notice of Reliance and supporting exhibits, TTABVUE #57; (d) rebuttal testimony declarations of Mya Thomae and Naomi O'Grady with exhibits, TTABVUE #s 90 and 91; and (e) Rebuttal Notice of Reliance and supporting exhibits, TTABVUE #93.

[1] Meridian took live testimony from Dr. Young after Opposer identified him, along with several other individuals, as relevant consumers *for the first time* in the Rebuttal Declaration of Naomi O'Grady. Because Opposer's identification of Dr. Young at this stage constituted inappropriate surprise, *Weiner King, Inc. v. Wiener King Corp.*, 204 U.S.P.Q. 820, 828 (Fed.Cir. 1980), Meridian's examination of this one (and only one) consumer was proper. *See,* TBMP § 707.03. Regardless, Opposer has relied on Dr. Young's testimony throughout its brief, and as a result, it has waived any objection it could have made to Dr. Young's testimony.

BACKGROUND FACTS

Since is founding in 1977, Meridian has operated in the clinical diagnostic field, manufacturing tests to detect the presence of infectious diseases in human patients. It has been a leader in this field since it pioneered its first test for *C. difficile* in 1992. Declaration of Kenneth J. Kozak, ¶ 5, TTABVUE #80. Meridian's products are used by individuals working within a clinical diagnostic laboratory. Kozak Dec., ¶ 12. A typical clinical diagnostic laboratory contains a number of specialized departments; for example Microbiology, Infectious Disease, Chemistry, Hematology, Special Chemistry, etc., and each specialized department has a manager or supervisor, with a "clinical director" – the relevant consumer of Meridian's products – managing these individuals. *Id.* at ¶ 7-11. The products used in clinical diagnostic labs must be cleared by the Food & Drug Administration (FDA) for in vitro diagnostic use and are referred to as "IVD" products. *Id.* at ¶ 12. IVD products are different from "Research Use Only" or "RUO" products which do not require FDA clearance because they cannot be used in the clinical diagnosis of human patients except in certain controlled, regulated circumstances. *Id.* at ¶ 21.

In vitro diagnostic products are defined as "those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae." 21 C.F.R. § 809.3. FDA regulations mandate strict compliance with the IVD marking requirement except in cases where: (1) a product has an investigational device exemption (IDE) which "applies to all clinical investigations of devices to determine safety and effectiveness;" (2) a product "is being shipped or delivered for product testing prior to full commercial marketing," in which case the product must carry the legend, "For Investigational Use Only;" or (3) a product is "in the laboratory research phase of development, and not represented as an effective in vitro

diagnostic product," in which case the product must carry the legend, "For Research Use Only. Not for use in diagnostic procedures." 21 C.F.R. § 809.10 (c); 21 C.F.R. § 812.2(a). IVD and RUO products are, therefore, mutually exclusive, *legally*, under FDA regulations.

Meridian applied to register its ILLUMIGENE mark on November 17, 2008. This is Meridian's priority date in this case. Subsequently, Meridian applied to register its ILLUMIGENE MOLECULAR SIMPLIFIED & design mark on April 1, 2009. These applications matured into Registration Nos. 3868081 and 3887164 on October 26 and December 7, 2010, respectively. In addition, Meridian applied to register its ILLUMIPRO and ILLUMIPRO-10 marks under Serial Nos. 77/768176 and 77/775316 on June 25 and July 7, 2009, respectively. Meridian's ILLUMIGENE product is a diagnostic test kit which tests for infectious diseases. The ILLUMIPRO product is the small device upon which the ILLUMIGENE tests are read. Declaration of Vecheslav A. Elagin, ¶ 9-14, TTABVUE #79. Both are FDA-cleared as IVD products. Meridian first advertised its ILLUMIGENE and ILLUMIPRO products on April 19, 2009 at the Clinical Virology Symposium in Daytona Beach, Florida. Kozak Dec. ¶ 55.

Meridian has traditionally marketed and sold its products, and specifically markets and sells its ILLUMIGENE and ILLUMIPRO products, to hospitals and clinical diagnostic laboratories. *Id.* at ¶ 12-15. The consumers of these products are highly educated and sophisticated individuals who deal with patient health issues on a daily basis. *Id.* at ¶ 32-41. During the purchasing process, the consumer becomes very familiar with Meridian's product offerings and capabilities. *Id.* at ¶ 34-41. Meridian negotiates extensively with its consumers regarding pricing, supply, and timing of product delivery. *Id.* In addition, the consumer rigorously analyzes the capabilities of Meridian's products to determine whether they fit the workflow of that specific clinical diagnostic lab. *Id.* Not until a contract is concluded and the

product portfolio analyzed for suitability does a consumer purchase Meridian's ILLUMIGENE and ILLUMIPRO products. *Id.* Meridian's products are comparatively inexpensive; its ILLUMIGENE products are priced between $25 and $60 per test. Its ILLUMIPRO reader is included *at no additional charge* with the initial purchase of an ILLUMIGENE test kit. *Id.* at 44.

Opposer started business in 1998 as a company manufacturing products for use in large scale genetic analysis. Declaration of Karen Possemato, ¶ 7, TTABVUE #66. Opposer has been recognized traditionally as a human genetic sequencing company, offering resources to research institutions to, e.g., sequence the human genome. Elagin Dec. ¶ 18-28; Kozak Dec. ¶ 27-31. On April 28, 2010, Opposer received its first FDA clearance to market a product as an IVD product. Declaration of Gregory F. Heath, ¶ 14, TTABVUE # 64. Up to that time, Opposer offered *exclusively* RUO products. The results of its foray into this new, clinical diagnostic space were decidedly mixed, as Opposer's first FDA-cleared product was discontinued only a short time later, and it was not until November of 2013 that Opposer received additional FDA clearances to market just a handful of new, IVD products. Dec. 4, 2014 Naomi O'Grady Dep. Tr., TTABVUE #83, at 15:10-11; Opposer's Notice of Reliance, Ex. 39, TTABVUE #57. Growing pains were to be expected, however, because Opposer had started playing in virgin territory which required it to adopt entirely new, FDA-regulated manufacturing and product development processes. *See,* Section II(C), *infra*. Nevertheless, all of these growing pains were experienced *after* Meridian entered the clinical diagnostic market with its ILLUMIGENE product, and some *33 years after* Meridian had first entered this market generally. Specifically, the clinical diagnostic space was not within Opposer's natural zone of expansion in November of 2008.

Opposer owns three registrations for its ILLUMINA mark dating back to 2000. All of these registrations describe goods and services in the scientific and medical research fields

which are irrelevant to this proceeding. On May, 28, 2009, Opposer applied to register its ILLUMINADX brand which was intended for use in connection with its fledgling clinical diagnostic business.[2] While Opposer has since applied this mark to its handful of IVD products, according to its 2013 Annual Report, the clinical diagnostic business was still *immaterial* to its bottom line.[3] Nevertheless, even Opposer's *de minimis* business in the clinical diagnostic space arrived well after November 17, 2008. Even today, Opposer advertises that its products are for Research Use Only except in certain specific instances. *See,* Section II(B). As a result, the relevant consumer likely still views Opposer as a human genetic research company today.

Opposer markets its products primarily to large, well-funded academic institutions and medical research labs, and in a limited number of cases to high-complexity, CLIA-certified labs within these organizations.[4] Kozak Dec. ¶ 16, 21-22. CLIA labs produce a unique, clinical diagnostic product known as a "laboratory developed test" or LDT. Sometimes called "home brews," LDTs are in-house diagnostic assays which are built from assorted, third party life science components, including Opposer's traditional RUO products, by the personnel working in the CLIA lab. Elagin Dec. ¶ 28. The lab itself then uses this self-constructed diagnostic assay for purposes which can include obtaining a clinical diagnostic result under controlled conditions. *Id.* However, Opposer cannot and does not influence the construction, marketing, or use of the LDT. Dec. 4, 2015 O'Grady Dep. Tr., at 92-94. Opposer's consumers, including those sourcing products for use in the CLIA-certified labs, are also well educated and extremely

[2] Opposer argues it owns two other trademarks which begin with the prefix, "ILLUMI-," but the record fails to prove this assertion.

[3] *See,* https://www.illumina.com/content/dam/illumina-marketing/documents/company/investor-relations/IlluminaInc-2013-10K.pdf

[4] CLIA is an acronym for Clinical Laboratory Improvement Amendments, a set of regulations implemented by the Centers for Medicare and Medicaid Services. 42 CFR § 493.1253(b)(2). When a laboratory develops a test system such as an LDT in-house without receiving FDA clearance or approval, CLIA prohibits the release of any test results prior to the laboratory establishing certain performance characteristics relating to analytical validity for the use of that test system in the laboratory's own environment.

sophisticated – no less sophisticated than Meridian's consumers. Dec. 4, 2014 Possemato Dep. Tr., TTABVUE #85, at 73:18-74:21. The purchasing process associated with Opposer's products is also a detailed one, and Opposer even offers its customers a scientific consultant to assist them with the process. Dec. 4, 2015 O'Grady Dep. Tr., at 107:3-116:21. Further, Opposer's products are extremely expensive; ranging from $95,000 on the low end to more than $250,000 on the higher end, and these prices do not include the cost of consumables. Possemato Dep. Tr., at 53:16-54:11.

CLIA-certified labs do not use IVD products in constructing LDTs, and as a result Meridian does not offer its ILLUMIGENE or ILLUMIPRO products (both of which are IVD products) to these labs. Kozak Dep. ¶ 22. Opposer is not a competitor of Meridian and does not offer goods or services to the same consumers. *Id.* at ¶ 16-31.

For more than 6 ½ years, Meridian and Opposer have marketed and sold their ILLUMIGENE and ILLUMINA products without any reported instances of confusion. *See,* Section II(I). Similarly, during this time the parties have also marketed and sold products bearing marks using the same prefix, "TRU-," again without any reported instances of confusion. *See,* Section II(K). Clearly, confusion is unlikely in this case.

SUMMARY OF ARGUMENT

Meridian has priority over Opposer in the clinical diagnostic space by virtue of its November 17, 2008 filing date attributable to its ILLUMIGENE application and its April 19, 2009 first use date of its ILLUMIPRO marks. By its own admission, Opposer's ILLUMINA marks recite products and services in the scientific and medical research fields – fields which are entirely separate from the clinical diagnostic space – and they are therefore irrelevant to

priority. Opposer's ILLUMINADX mark represents Opposer's first foray into the clinical diagnostic space, and it came into existence after Meridian's priority date.

Because Meridian has priority over Opposer, the Board need not consider likelihood of confusion. Regardless, the parties' marks are dissimilar because they share only the weak ILLUMI- prefix, and the remaining elements of the parties marks are sufficiently different from one another to avoid confusion particularly when considering widespread third-party use of similar marks in the relevant field. In addition, the parties' respective goods and services are dissimilar, so much so that they are legally different pursuant to strict FDA regulations. Specifically, Meridian manufactures and sells IVD products, while Opposer manufactures and sells RUO products. By virtue of the regulations applicable to both categories of products, they are dissimilar, not complementary with one another, and mutually exclusive.

Opposer admits that it started as a research company, and the record confirms that the clinical diagnostic market was not within its natural zone of expansion as of November 17, 2008. Any evidence submitted by Opposer to prove its zone of expansion argument which is dated after this time is irrelevant and cannot be considered. Opposer's purported evidence from the relevant time period is both insufficient and insubstantial under applicable precedent. Opposer cannot rely on announcements of "planned" activities in the clinical diagnostic space because it fails to demonstrate these plans resulted in any actual, meaningful activity. Further, the record is completely devoid of any evidence suggesting that the relevant consumer understood the clinical diagnostic space to be within Opposer's natural zone of expansion, and because this consumer awareness is critical to the analysis, its absence from the record is fatal to Opposer's position.

The similarity of trade channels is not determinative in this case, to the extent Opposer has demonstrated any meaningful overlap. The relevant consumers of the parties are highly educated and sophisticated, and great care is taken when the relevant consumer makes a purchasing decision involving either of parties' respective products. A variety of factors are carefully considered during this process, and because patient health is at stake should confusion occur, the relevant consumer's awareness to subtle differences between trademarks is heightened. In addition, Opposer's has failed to demonstrate its mark is famous for Section 2(d) purposes – in any market – because its evidence does not prove any consumer awareness in the relevant market, and certainly not the level of consumer recognition required to prove fame. Moreover, Opposer cannot prove it owns a family of marks because it has only demonstrated that it owns, at most, 2 marks which share a common component.

Most damaging to Opposer's case is the fact that the parties have coexisted for a period of 6 ½ years without *any* reported instances of actual confusion. The absence of actual confusion for this length of time is strong evidence that confusion is unlikely. Any likelihood of confusion is further lessened by the fact that Opposer uses its ILLUMINA mark as a house brand whereas Meridian uses its ILLUMIGENE and ILLUMIPRO marks as product marks. Both parties' witnesses have admitted this distinction is relevant, particularly in the way in which the parties' marks are encountered by the relevant consumer during the purchasing process. Finally, the parties' TRU-formative marks also coexist with one another under nearly identical facts, and this fact proves the parties marks can also coexist here.

ARGUMENT

I. Meridian's ILLUMIGENE Registrations Have Priority Over Opposer's Marks in the "Clinical Diagnostic" Space.

In an *inter partes* proceeding, an owner of an ITU-based registration is entitled to rely on the filing date of the application as a constructive use date. *Chicago Bears Football Club, Inc. v. 12th Man/Tennessee LLC*, 83 USPQ2d 1073 (TTAB 2007). Meridian's November 17, 2008 filing date for Registration No. 3868081, ILLUMIGENE, is its priority date in this case. As of November 17, 2008, Opposer did not offer any FDA-cleared IVD products for use in the clinical diagnostic market which Meridian has occupied consistently since 1977. Kozak Dec. ¶ 5, 11; Elagin Dec. ¶ 27.

All three of Opposer's registrations for ILLUMINA recite products and services that are to be used for scientific or medical research purposes only. Elagin Dec. ¶ 13-25; May 12, 2015 O'Grady Dep. Tr. TTABVUE #97, at 169:5-170:12, 174:3-176:8, 178:7-179:9, and 193:9-197:9. The distinction between RUO products and those which are FDA-cleared for IVD uses in a clinical diagnostic setting is highly significant. Not only are the ultimate purchasers and users of these two types of products different, but under FDA regulations, RUO products must not be marketed for IVD purposes. May 12, 2015 O'Grady Dep. Tr., at 38:14-39:5 and 159:4-8. Opposer offered only RUO products through at least early 2010 and was forbidden to market or advertise the purchase of those products for IVD use by a clinician. *Id.*

Opposer's recitations are the only competent evidence in the record that potentially speak to Opposer's alleged priority in this case, and those recitations indisputably do not include diagnostic products and services based on Opposer's own sworn statements to the Trademark Office. Meridian does not dispute that Registration Nos. 2471539, 2632507, and 2756703 – all for the mark ILLUMINA – predate Meridian's *filing* dates in this case. However, as

explained fully in Section II(B), these ILLUMINA registrations identify RUO products and services meant for the scientific research market, not the IVD products Meridian sells in the clinical diagnostic market. Elagin Dec. ¶ 11-17. As a result, the ILLUMINA registrations do not confer priority on Opposer in the clinical diagnostic space which Meridian has historically occupied. Further, as explained in Section II(H), neither "Illuminotes" or "Illumicodes" are valid trademarks, and therefore neither affects priority.

The Board need not take Meridian's word for it on the priority issue. Rather, Opposer's own statements and own actions before the Trademark Office establish conclusively that Opposer was a research company prior to Meridian's priority date for ILLUMIGENE and entered the diagnostic market only afterward with its ILLUMINADX brand. The relevant dates from Opposer's ILLUMINA registrations are as follows:

Mark	Registration No.	First Use Date	Section 8 & 15 Date
ILLUMINA	2471539	February 1999	June 1, 2007
ILLUMINA	2632507	February 23, 2001	December 10, 2007
ILLUMINA	2756703	January 9, 2003	September 23, 2008

As the Board is aware, when a Section 8 Affidavit is filed, the registrant asserts – under penalty of perjury – that it is using its mark in connection with *all* of the goods listed in the Section 8 Affidavit, and if it is not, it must either delete the unused goods from its recitation or provide reasons for its excusable non-use. TMEP §§ 1604.09 – 1604.11. Similarly, when a Section 15 Affidavit is filed, the registrant asserts – under penalty of perjury – that it has continuously, for a period of 5 years following the date of registration, used its mark in connection with *all* of the goods listed in the Section 15 Affidavit. TMEP §§ 1605.04 – 1605.05. Thus, if a Section 8 & 15 Affidavit is filed against *all* of the goods/services that were listed in the original registration,

this means that *all* those goods/services were in use for at least 5 consecutive years prior to the filing date of the Affidavit.

Opposer filed Section 8 & 15 Affidavits on *all* of the goods/services originally listed in Registration Nos. 2471539, 2632507, and 2756703. These Affidavits were filed in June 2007, December 2007, and September 2008, respectively, meaning Opposer had used *all* the goods/services identified therein continuously since at least as early as June 2002, December 2002, and September 2003. The effect of the Section 8 & 15 Affidavits asserting use of *all* recited goods/services continuously since 2002-2003, combined with the admission that Opposer had *no* use in the clinical diagnostic space at the time[5], means that Registration Nos. 2471539, 2632507, and 2756703 must be interpreted to describe products and services *exclusively* in the "scientific and medical research" fields, *not* in the clinical diagnostic field.

As a result, Opposer can only rely on the priority conferred by its ILLUMINADX mark, Registration No. 4053668, because this is the oldest of its registrations which refers to "clinical diagnostic" products and "clinical diagnostic purposes." Thus, it is inaccurate and misleading for Opposer to allege it has some type of "blanket" priority to assert against Meridian. In the relevant space, Meridian enjoys priority by virtue of both its ILLUMIGENE registrations and its ILLUMIPRO applications. The November 2008 priority date for the ILLUMIGENE mark precedes Opposer's May 28, 2009 priority date for ILLUMINADX. Further, Meridian actually exhibited its ILLUMIGENE and ILLUMIPRO products at both the Clinical Virology Symposium (CVS) from April 19-22, 2009 in Daytona Beach, Florida and the American Society for Microbiology (ASM) conference in Philadelphia, Pennsylvania from May 17-21, 2009. Kozak

[5] Opposer's only witness on this point, Naomi O'Grady, admitted she was unaware of any products branded ILLUMINA used in clinical diagnostic laboratories from 2000-2006, and further admitted she knew nothing about Opposer's Section 8 & 15 Affidavits. May 12, 2015 O'Grady Dep. Tr., at 167:8-18.

Dec. ¶55, and Exs. F, G, and H thereto (the ILLUMIPRO-10 mark is printed on the reader which is shown in the trade show displays). This evidence is uncontroverted and unchallenged by Opposer. From this, Meridian has demonstrated its actual first use date of ILLUMIGENE, ILLUMIGENE MOLECULAR SIMPLIFIED & design, ILLUMIPRO, and ILLUMIPRO-10 is at least as early as April 19, 2009. Meridian's actual use predates Opposer's May 28, 2009 priority date for ILLUMINADX, Opposer's oldest mark in the clinical diagnostic space.

Opposer's only remaining argument regarding priority is that contrary to Opposer's marketing, certain extremely sophisticated labs could have selected Opposer's RUO components for inclusion in LDTs beginning in 2007. May 12, 2015 O'Grady Dep. Tr., at 39:20-40:3. But Opposer offers absolutely no *evidence* of how prevalent this practice was, and it therefore cannot demonstrate it was involved in the clinical diagnostic market in any meaningful sense. *Id.* at 118:8-16, 161:19-162:6. Similarly, although Opposer generally asserts "awareness" of its ILLUMINA brand by consumers in the clinical diagnostic space prior to November 2008, it offers no market studies and no actual evidence of consumer awareness. May 12, 2015 O'Grady Dep. Tr., 265:11-266:22.[6]

The truth is that Opposer's ILLUMINA recitations place its products and services squarely and exclusively in the scientific and medical research markets for the purposes of priority, and its provable real-world evidence only verifies this fact. Quite simply, Meridian has priority in the clinical diagnostic space.

[6] Opposer's argument with respect to LDTs is further debunked in Section II(B), *infra*.

II. There is No Likelihood of Confusion Between the Parties' Marks.

Because Meridian has priority in this case, the Board need not even address whether there is a likelihood of confusion. Regardless, and without waiving its position on the issue of priority, Meridian provides the following likelihood of confusion analysis.

Under *In re E. I. du Pont de Nemours & Co.*, the Board will consider the following factors, to the extent relevant evidence is present in the record: (1) the similarity of the marks in their entireties as to appearance, sound, connotation, and commercial impression; (2) the similarity and nature of the goods or services as described in an application or registration or in connection with which a prior mark is in use; (3) the similarity of established, likely-to-continue trade channels; (4) the conditions under which and buyers to whom sales are made, i.e. "impulse" versus careful, sophisticated purchasing; (5) the fame of the prior mark; (6) the number and nature of similar marks in use on similar goods; (7) the nature and extent of any actual confusion; (8) the length of time during, and conditions under which, there has been concurrent use without evidence of actual confusion; (9) whether a house mark, "family" mark, or product mark is at issue; and (10) any other established fact probative of the effect of use. *In re E. I. du Pont de Nemours & Co.*, 177 U.S.P.Q. 563 (C.C.P.A. 1973). Weighing these factors, confusion is not likely.

(A) The Parties' Marks are Dissimilar in Sound, Connotation, and Appearance.

For the purposes of determining likelihood of confusion, the marks must be compared in their entireties and not dissected into their component parts. *China Healthways Inst., Inc. v. Wang*, 83 U.S.P.Q.2d 1123 (Fed. Cir. 2007). However, the Board may give less weight to those weak elements of the mark such as prefixes and suffixes. *Al-Site Corp. v. VSI Int'l, Inc.*, 50 U.S.P.Q.2d 1161 (Fed. Cir. 1999); *Swatch AG v. M.Z. Berger & Co.*, 108 U.S.P.Q.2d 1463, 1470

(T.T.A.B. 2013). Additionally, the Board must consider the marks in context, as consumers would see them in the marketplace. *Fort James Operating Co. v. Royal Paper Converting, Inc.*, 83 U.S.P.Q.2d 1624, 1629 (T.T.A.B. 2007). In the case of a standard character mark, the Board will consider how it is actually used. *In re Vittera, Inc.*, 101 U.S.P.Q.2d 1905 (Fed. Cir. 2012). Even if the dominant portion of both marks is the same, confusion is not likely if the matter common to the marks is unlikely to be perceived by purchasers as distinguishing source because it is diluted. S*ee, e.g., Citigroup Inc. v. Capital City Bank Group, Inc.*, 94 USPQ2d 1645 (TTAB 2010).

As Meridian demonstrates in Section II(G), infra, the prefix "ILLUMI-" is weak and entitled to a narrow scope of protection. This fact impacts the "similarity of marks" factor because the marks in this case are similar only to the extent that they share this diluted "ILLUMI-" prefix. Because the shared material is diluted, any similarities must be discounted somewhat, and the Board should focus instead on the *entirety* of the parties' marks.

Even if the Board disagrees with the impact of these third party registrations, the marks are still not sufficiently similar for consumers to be confused. Opposer's marks are ILLUMINA and ILLUMINADX.[7] Meridian's marks are ILLUMIGENE, ILLUMIGENE MOLECULAR SIMPLIFIED & design, ILLUMIPRO, and ILLUMIPRO-10. Meridian's ILLUMIGENE mark contains the letters "G-E-N-E" which are not found in either of Opposer's marks. Similarly, Meridian's ILLUMIPRO mark contains the letters "P-R-O" which are also not found in either of Opposer's marks. Also, Opposer's ILLUMINADX mark contains the letter "X." The letter "X" is not commonly used in the English language and creates a specific visual impression on the consumer. In addition, Meridian's ILLUMIGENE MOLECULAR SIMPLIFIED & design mark

[7] Opposer presumes without argument or foundation that it has properly pleaded and proven the existence of two additional, unregistered marks – "Illuminotes" and "Illumicode" (alternately displayed as "Illumicodes"). Opposer's Brief, p. 24-27. As discussed in Section II(H), *infra*, Opposer has failed to demonstrate that the terms "Illuminotes" or "Illumicode[s]" are valid marks or that it has the exclusive right to use either one. Regardless, these "non-trademarks" are no more similar to Meridian's marks than Opposer's "real" trademarks.

contains two additional words – MOLECULAR and SIMPLIFIED – plus a design element, none of which is found in either of Opposer's marks. While arguably the word ILLUMIGENE is the dominant element of Meridian's composite mark, the other elements cannot be ignored in comparing the marks. The result is that the parties' marks are materially different in appearance. Minimizing the similarities attributable to the diluted prefixes, the differences in appearance are even more stark. Opposer's marks end in -NA and -NADX. Conversely, Meridian's marks end in -GENE and -PRO. The endings are completely different in appearance.

The differences also render the sound of the parties' marks different. Opposer's ILLUMINA mark ends in a short "uh" sound, while Meridian's ILLUMIGENE and ILLUMIPRO marks end in long vowel sounds, "ee" and "oh" respectively. Further, Meridian's ILLUMIGENE mark features a soft "g" sound in the fourth syllable, while its ILLUMIPRO mark features a hard "p" sound in the fourth syllable. Neither sound is present in either of Opposer's marks. In addition, Opposer's ILLUMINADX mark ends in the uncommon "ecks" sound which is not present in Meridian's marks. The marks are therefore different in sound as well.

With respect to connotation, it should be noted that ILLUMINA is Latin for "enlighten." *See,* http://www.latin-dictionary.net/search/latin/illumina. The "N," which is present in Opposer's marks but absent in Meridian's, is the part of the Latin root giving the word this meaning. The "DX" ending found in the ILLUMINADX mark is commonly used as shorthand for "diagnosis." *See,* http://www.medilexicon.com/medicaldictionary.php?t=27123. Conversely, both ILLUMIGENE and ILLUMIPRO are both coined words which have no specific meaning. The connotation of the marks, therefore, is different.

Citing to the KIDWIPES case, Opposer argues that "the ILLUMI prefix…is the dominant portion of [all of the parties'] mark[s]" simply because it is the first element of the marks.

Opposer's Brief, p. 25.[8] Here, while both Opposer and Meridian both use marks that begin with "ILLUMI-," Opposer has failed to prove that this similarity, in and of itself, is relevant. Further, as explained in Section II(G), Opposer is just one of many entities to use an "ILLUMI-" prefix in the relevant field. Given the facts, "ILLUMI-" cannot properly be viewed as the dominant element of any of the marks in this case. Accordingly, this factor favors Meridian.

(B) Meridian's IVD Goods and Opposer's RUO Goods and Services are Legally and Practically Dissimilar.

Meridian's recitations all explicitly reference diagnostic kits and diagnostic uses.[9] Opposer's ILLUMINA recitations stand in stark contrast. Registration No. 2632507 clearly references goods "for scientific or medical *research*" and "scientific and medical *research*" services. While the remaining portions of this recitation contain terminology that is complex, they are undeniably limited to *research*, not diagnostics, a market delineation that is strictly enforced by the FDA. This recitation also establishes that, in Opposer's parlance, "scientific" and "medical" have different meanings – otherwise Opposer would not use both words separated by "or." Based on this construction, it is clear that Registration No. 2756703 recites goods that are not in the medical field – they are explicitly limited to "*scientific* equipment and instruments." Registration No. 2471539 describes custom-made chemical-sensing platforms

[8] *Presto Products., Inc. v. Nice-Pak Products., Inc., 9 USPQ2d 1895 (TTAB 1988),* was not a case about marks sharing a similar prefix. Registrant's mark in *Presto Products* was KID STUFF whereas Applicant's mark was KIDWIPES. The dominant element of both marks in *Presto Products* was an actual word – not a prefix. Not only was Registrant's mark comprised of two separate words, but Applicant's mark was comprised of two separate words telescoped into a single word. Such is not the case here, as the parties' marks do not consist of individual words that can be separated. In addition, the Board's determination was heavily influenced by the fact that the parties were the *only* parties which used a KID-formative mark on the goods at issue.

[9] The recitations of Registration No. 3868081, ILLUMIGENE, and Registration No. 3887164, ILLUMIGENE MOLECULAR SIMPLIFIED & design, are identical, and both read: "*diagnostic kits consisting of molecular assays for use in disease testing and treatment of gastrointestinal, viral, urinary, respiratory and infectious diseases.*" The recitations of Serial No. 77/768176, ILLUMIPRO, and Serial No. 77/775316, ILLUMIPRO-10, are identical, and both read: "*diagnostic machine, namely, a stand alone closed heater and turbidity meter to be used for the amplification and detection of a closed tube molecular assay.*"

made to the specifications of others. This recitation describes products which are very different from the single-purpose diagnostic kits and readers described in Meridian's recitations.

Where the terminology in a recitation is unclear, a party may provide extrinsic evidence to show that the recitation has a specific meaning to members of the trade. *In re Trackmobile Inc.*, 15 USPQ2d 1152, 1154 (TTAB 1990). While evidence of actual use cannot be used to redefine the nature of an identification, extrinsic evidence can be consulted to remove uncertainty. *In re Continental Graphics Corp.*, 52 USPQ 2d 1374 (TTAB 1999). The recitations of goods and services in Opposer's Registration Nos. 2471539, 2632507, 2756703, and 4053668 are technically complex and vague, and understanding their meaning "requires knowledge about [Opposer's] actual activity in the marketplace and product offerings as context." Elagin Dec., ¶ 9-10. Indeed, Ms. Possemato, agreed with premise, admitting she did not fully understand certain aspects of Opposer's recitations. Possemato Dep. Tr., 56:7-57:4. Accordingly, the Board should consider extrinsic evidence explaining the exact nature of the goods and services at issue.

The only admissible evidence on this topic comes from Vecheslav A. Elagin, Meridian's Executive Vice President, Research and Development. Although Opposer attempted to offer a declarant on the meaning of its recitations, she admitted she was simply explaining what they meant to her personally, reading them today, and she made no attempt to consider the meaning from the perspective of the relevant consumer or at the time of filing. May 12, 2015 O'Grady Dep. Tr., 144:6-146:14. In any event, she articulated no experience or education that would render her impression better or more appropriate than Dr. Elagin's. *Id.*

Dr. Elagin explains in detail why someone with the requisite background to understand the product and service recitations at issue would understand that Opposer's ILLUMINA registrations apply to different products and services from Meridian's recitations. Elagin Dec. ¶

11-16. He confirms the recitations illustrate the divide between Opposer's research products and services and Meridian's diagnostic products and also explains other relevant differences between the recitations. *Id.* Thus, on the face of the recitations, and from the standpoint of one familiar with the technical language therein, the goods and services at issue are different.

The way the products are actually marketed confirm Dr. Elagin's interpretation. The Board will note that each and every ILLUMIGENE and ILLUMIPRO product is marked as an IVD (in-vitro diagnostic) product, with the exception of its pre-FDA clearance products which were marked IUO (investigational use only). In contrast, every single one of Opposer's products, services, and pieces of supporting marketing material, prior to April 2010, are marked RUO (research use only). Even today, the following statement is found in the footer on every page of Opposer's website: ***For Research Use Only. Not for use in diagnostic procedures (except as specifically noted)***. *See,* http://www.illumina.com.

On April 28, 2010, Opposer received its *first* FDA clearance for an IVD product – its Veracode Genotyping Test for Factor V and Factor II using the BeadXpress system.[10] Prior to that date, Opposer could not – without violating FDA regulations – market, advertise, distribute, or sell products to be used for in vitro diagnostic purposes in a clinical setting. Accordingly, prior to April 2010, Opposer's products were not in vitro diagnostic products, and they were not clinical diagnostic products. In fact, Opposer adopted an entirely new brand – ILLUMINADX – to mark its transition from RUO to IVD products. This brand, an application for which was not filed until May 28, 2009, was not used in commerce until the pre-market testing of its Veracode Factor V/II test which occurred in March of 2010. Indeed, Opposer's application to register ILLUMINADX is the first of Opposer's marks which includes a reference

[10] These products, including the BeadXpress system, have since been discontinued by Opposer. Elagin Dec. ¶ 36-37.

to "clinical diagnostic" in its recitation. The two markets are separate in terms of the relevant consumers, and are kept separate by strict FDA regulation. *See,* 21 C.F.R. § 809.3; 21 C.F.R. § 809.10 (c); 21 C.F.R. § 812.2(a); May 12, 2015 O'Grady Dep. Tr., at 38:14-39:5 and 159:4-8.

Even Opposer's own testimony supports Meridian's position that the goods are dissimilar. Under cross examination, Karen Possemato discussed the BeadXpress system on which Opposer's IVD products for Factor V/II were deployed.[11] She explained that the BeadXpress product offered multi-plexing on the level of 100,000. Dr. Elagin explained that "multiplexing" refers to the number of analytes that can be detected from a sample at one time. Elagin Dec. ¶ 33. Ms. Possemato referenced a product offered by a company called Luminex, which she asserted was not competitive with Opposer's products, because the product only offered a level of multiplexing of 100 or 200. Possemato Dep. Tr., at 86:3 – 87:14. Ms. Possemato stated that comparing Opposer's product to the Luminex product ***would be like comparing "apples and oranges."*** Possemato Dep. Tr., at 87:6-7. From a multiplexing standpoint, Meridian's ILLUMIGENE product has a multiplexing level of 1. In other words, it has no multiplexing capability whatsoever. As a result, if a product with multiplexing of 100,000 is as different from a product with multiplexing of 100 as an apple and an orange, the ILLUMINA product is an apple, and the ILLUMIGENE product is a banana. Elagin Dec. ¶ 32-35.

Opposer asserts that its RUO products are nonetheless similar to IVD products by arguing that its RUO products can be used in LDTs. Due to the applicable regulations, the validity of a specific LDT is limited to the specific conditions, staff, equipment and patient population of the particular laboratory, so the findings of these LDTs are not meaningful

[11] Note that this VeraCode product could not have been related to the goods or services identified in Opposer's ILLUMINA recitations because Opposer had not acquired the company which made this product until 2005. Opposer's Brief p. 39.

outside of the laboratory that did the analysis.[12] Further, the consumer-facing "output" of an LDT, if any, is a test report issued by the laboratory itself, and in this sense an LDT is a service, not a product. None of the manufacturers of the individual RUO components used in constructing the LDT has any influence or control over the report or the construction of the LDT, and the LDT does not carry the brands of the component manufacturers. Elagin Dec. ¶ 29-30; Kozak Dec. ¶ 23-25; O'Grady Dep. Tr., at 91:11-94:16. In the LDT context, then, Opposer is nothing more than a component manufacturer, and it is well-settled that use of a trademark on a component does not equate to use of the trademark on the finished product in which the component is included where the finished product does not carry the component manufacturer's brand. *See, In re Albert Trostel & Sons Co.*, 29 U.S.P.Q.2d 1783 (T.T.A.B. 1993); *Matsushita Electric Industrial Co., Ltd. v. Sanders Associates, Inc.*, 177 U.S.P.Q. 720 (T.T.A.B. 1973).

RUO products and IVD products are legally different, both in a vacuum and in the context of an LDT. Simply stated, an IVD product is a complete, finished, diagnostic product. IVD products are used "right out of the box" by a consumer without needing to use any additional components. They cannot be combined with other IVD products to create an LDT because IVD products are not FDA-cleared to be used in combination with other IVD products. More to the point, LDTs are not (and cannot be, under the relevant regulations) built with IVD products. Elagin Dec. ¶ 30. Contrast this with an RUO product which, because it has not been approved by the FDA to be used in obtaining a diagnostic result by itself, must necessarily be combined with other RUO products by a CLIA-certified lab in building an LDT. Put differently, a consumer will not purchase an IVD product to create an LDT because the IVD product is already available as a pre-packaged unit to render the clinical diagnostic answer for which the

[12] See, http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia/

LDT would be built. The lab running the test would not need to be CLIA-certified to use the IVD product. Accordingly, the goods and services set forth in the parties' recitations are wholly dissimilar, are certainly not related or complementary in any way, and are directed to two very different markets; the research market on one hand and the clinical diagnostic market on the other.

(C) The Clinical Diagnostic Field Was Not Within Opposer's Natural Zone of Expansion as of Meridian's November 17, 2008 Priority Date.

The zone of expansion analysis asks whether there is a strong possibility that the opposer will expand its offerings of goods and services so as to compete with the applicant. *Homeowners Group, Inc. v. Home Marketing Specialists, Inc.*, 18 U.S.P.Q.2d 1587 (6th Cir. 1991); *E & J Gallo Winery v. Gallo Cattle Co.*, 967 F.2d 1280, 1293 (9th Cir. 1992). The natural zone of expansion is defined to include those things that *consumers* would expect might come from the same source. *J.C. Hall Co. v. Hallmark Cards, Inc.*, 114 U.S.P.Q. 435 (CCPA 1965). If the zone of expansion is proved, the first user can "tack on" its prior use on different goods to achieve priority over the junior, intervening user in the new space. 3 McCarthy on Trademarks and Unfair Competition § 20:17. However, mere speculation or claims about future intentions are not sufficient evidence of expansion. *Surfvivor Media, Inc. v. Survivor Prods.*, 74 U.S.P.Q.2d 1621 (9th Cir. 2005). Further, evidence of insignificant expansion will be insufficient to support a zone of expansion argument. *M2 Software, Inc. v. Madacy Entertainment*, 72 U.S.P.Q.2d 1161 (9th Cir. 2005). Whether expansion is "natural" is a factual issue determined by the perception of *consumers* at the time of the junior user's first use of the senior user's trademark. *Brookfield Communications, Inc. v. West Coast Entertainment Corp.*, 50 USPQ2d 1545, 1554 (9th Cir. 1999).

Opposer asserts in its brief that "Illumina began as a research company." Opposer's Brief p. 38. Meridian agrees. As explained in Section I, *supra*, Meridian's first use date for

purposes of priority and expansion is November 17, 2008. Opposer must therefore prove that the clinical diagnostic space was within its natural zone of expansion as of November 17, 2008, and, more importantly, *that consumers were actually aware of this fact at that time*. Evidence in the record that is dated post-November 17, 2008 is fundamentally irrelevant for purposes of the zone of expansion analysis.[13]

After its irrelevant evidence is stripped away, Opposer's is left with the following assertions: (1) it acquired Veracode technology from CyVera in April, 2005 and publicized the application of this technology to diagnostics in 2006; (2) it hired Mickie Henshall in 2005 to fill a diagnostics role in the company; (3) it collaborated with deCODE Genetics, Inc. and ReaMetrix, Inc. to develop diagnostic tests in 2006; (4) it had plans to submit applications to the FDA for IVD products in 2006; (5) it "developed all of its Veracode products under 'design control;' (6) its products were used in a 2007 study at the University of Maryland funded by the Bill & Melinda Gates Foundation; (7) Dr. Steven Young testified that Next Generation Sequencing will be used in clinical diagnostics; (8) it "began the project for a CLIA-certified diagnostics services lab" in September 2008, a plan which it "announced by November 2008"; and (9) in January 2008, it internally re-organized to create a Diagnostics Business Unit.[14] Meridian discusses these assertions below.

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[13] The Board must therefore ignore all of the following: (a) the March, 2009 shipment of the BeadXpress device for clinical trials (Opposer's Brief, p. 40); (b) the September 2009 FDA submission (Id.); (c) the April 2010 FDA approval (Id.); (d) Exhibits 8, 9, 12-39 to Opposer's Notice of Reliance – all of which are dated after November 17, 2008; (e) Exhibits 40-44 to Opposer's Notice of Reliance – all of which are again dated after November 17, 2008; (f) Exhibits 45-54 to Opposer's Notice of Reliance – all of which are printouts of third party company websites dated April 9, 2012; (g) Illumina's 2007 purported collaboration with the Children's Hospital of Eastern Ontario (Opposer's Brief, p. 40) because this hospital is located in Canada; and (h) the purported "collaborative agreement with the Mayo Clinic" (Opposer's Brief, p. 40; O'Grady Dec. ¶20) because Opposer has provided no evidence as to when this "collaborative agreement" actually was entered into or whether it progressed beyond putting signatures on a piece of paper.

[14] Opposer also references a 2007 presentation entitled "*VeraCode Technology – From Research to Molecular Diagnostics*" which it asserts was presented "frequently." O'Grady Dec. ¶ 7. However, Opposer offers no *evidence* as to who attended these presentations (other than its *internal* "sales team").

The April 2005 acquisition of CyVera and its Veracode technology purportedly marks Opposer's first internal attempt to "pivot" from its foundations as a genetic sequencing and research company into the separate field of clinical diagnostics. Opposer's evidence in support of its publicity surrounding this technology is an article from the online site, Clinica, located at www.clinica.co.uk. Opposer's Notice of Reliance, Ex. 4, ILLUM-0165. This document is inadmissible hearsay that Opposer inappropriately offers to prove the truth of what is asserted in the article. The Board will no doubt also observe that this is a *foreign* publication. Opposer offers no evidence as to the U.S. readership of this material or any consumer awareness of it whatsoever. Further, the article states that Opposer's "BeadXpress diagnostic platform…is scheduled for market introduction before the end of the year [2006]." The record demonstrates that this obviously did not happen. It was not until April, 2010 that Opposer had an FDA-cleared, in vitro diagnostic product available to the public.

The "collaborations" with deCODE Genetics and ReaMetrix were "publicly" announced in May and July of 2006, respectively, the former in a story from an online publication called GenomeWeb, and the latter through one of Opposer's press releases. Opposer's Notice of Reliance, Exs. 3, 203. These, too, are inadmissible hearsay, and offer no support as to consumer awareness of their contents. Further, the announcements merely note that the companies "plan to develop" certain products. Opposer has offered no evidence that these "collaborations" ever bore any fruit in the form of marketable products. Without evidence to the contrary, it is likely that the deCODE Genetics and ReaMetrix "collaborations" suffered the same fate as Opposer's collaboration with EraGen Biosciences to develop a diagnostic test for herpes – the product was never actually developed, and EraGen was acquired by Opposer's competitor, Luminex, Inc. Dec. 4, 2014 O'Grady Dep. Tr., 157:10-165:15; Opposer's Notice of Reliance Ex. 304.

Opposer's Exhibit 304 is an internal document called "Diagnostics Portfolio Management Plan" dated [redacted] Indeed, Opposer first began trumpeting the coming of its "diagnostic" business in its 2006 Annual Report. The "it's coming soon!" party line carried on through its 2007 Annual Report, where its "emerging business in diagnostics" was touted; its 2008 Annual Report, referencing an "emerging opportunity in molecular diagnostics;" and its 2009 Annual Report, where Opposer stated that it will, "in the future…enter the market for molecular diagnostics." Meridian's Notice of Reliance, Ex. 2, ILLUM-2205, 2305, 2412, 2496. Yet despite all this "announcing," Opposer did not have a single FDA-cleared, IVD product on the market until May of 2010, and it had not even approved a corporate strategy to enter the relevant space until July of 2008. ILLUM-0658. Opposer publicly announced in January 2008 that it had reorganized

its company structure and created a Diagnostic Business Unit before it approved a strategy to actually create any products through this unit. Opposer's Notice of Reliance, Exs. 101-02, ILLUM-0558-0600. Then, it wasn't until January 21, 2009 that Opposer publicly "unveiled" its strategy to enter the molecular diagnostic market. Meridian's Notice of Reliance, Ex. 4, ILLUM-1577. All of this apparently occurred *after* Opposer "had a formal development program to seek regulatory approval for its BeadXpress system…for in-vitro diagnostic use" in place in 2006. Heath Dec. ¶ 13. Dr. Heath's unsupported statement, in this regard, frankly does not sync with the direct evidence in the record. Opposer has not explained how it could have had a full scale development program already in place before it had even adopted a strategy to enter this line of business. The hiring of Mickie Henshall in 2005 to "work exclusively on the marketing and promotion of Illumina's diagnostic products and services" is also inconsistent with the evidence presented, particularly if Opposer is somehow suggesting that this hiring – in and of itself –was meant to signal to the relevant consumer that Opposer was imminently about to start churning out clinical diagnostic products.

Indeed, statements from Opposer's own CEO directly contradict Opposer's revisionist history. Illumina CEO, Jay Flatley, stated *in 2010* that the company's first FDA clearance for a product was "a significant and exciting *transitional* step for Illumina into the diagnostics field" (emphasis added). May 12, 2015 O'Grady Dep. Tr., at 115:8-18 and at Dep. Ex. R. Mr. Flatley had also told investors in January of 2009 that "Illumina *plans* to enter the molecular diagnostic space by forging partnerships with customers, opening a new CLIA lab, and launching a research project to study cancer genomes" (emphasis added). *Id.* at 115:19-118:3 and Dep. Ex. S. Ms. O'Grady attempted to toe the party line that diagnostics was a mere continuation for

Opposer in 2009 – not a transition – but Ms. O'Grady ultimately had to concede that she "said something different" than Mr. Flatley. *Id.* at 222:6-223:4.

Opposer apparently expects the Board to conclude that despite needing 2 years from the time it first announced an "interest" in entering Meridian's market to actually "creating" a business unit within its company to "develop" these products, and a further 2 years before actually putting an alleged diagnostic product (its Factor V and Factor II test) on the market, Opposer should somehow be able to reserve the clinical diagnostic space for itself. Opposer has not cited to any precedent that would support such an assertion. Rather, applicable precedent holds that mere speculation or claims about future intentions are not evidence of expansion, and an inability to provide *concrete* evidence of expansion plans at the time the junior user began use indicates a finding against the senior user. *Surfvivor Media*, 406 F.3d 625. There must be a strong possibility of expansion into competing markets in order for the "zone of expansion" analysis to point towards a finding of infringement, and there is no "strong possibility" in the record as of November 17, 2008. *E & J Gallo Winery*, 967 F.2d 1280. Opposer cannot make a claim to a new market merely with public announcements that its products are "coming soon." Moreover, *none of Opposer's evidence speaks to the perception of consumers at the relevant time.*

Opposer's statement that it "developed all of its Veracode products under 'design control' is not only wildly misleading, it appears *false* based on a reading of Opposer's own evidence. As Mr. Kozak testified, "design control" is the terminology used to describe the process by which products are developed to meet the rigorous regulations for IVD products. Kozak Dec. ¶ 65. Strict compliance with FDA regulations is mandated during all phases of the product's development per 21 C.F.R. § 820.1 et seq. Kozak Dec. ¶ 66. Part of the design control

process is something known as "QSR compliance" (the FDA requires Quality System Regulation compliance in the manufacturing of devices that it clears for IVD use). Kozak Dec. ¶ 71. If a company has to change its existing manufacturing techniques in order to be QSR compliant, this fact suggests that the company did not plan to be in the IVD space from the outset. *Id.* As proof of its "design control" assertion, Opposer cites to Ex. 303, ILLUM-0579. This document is the "Veracode Launch Package" dated [redacted]

In addition to being inadmissible hearsay, the Gates Foundation study might be the biggest red herring in this entire case. Opposer uses this evidence in an attempt to prove that its products were used in 2007 to test for the same *C.difficile* pathogen as Meridian's first ILLUMIGENE product. However, the Gates Foundation study with the University of Maryland was an epidemiological research study which sought to "evaluate" several new technology platforms, including Opposer's Golden Gate technology (which was shortly thereafter discontinued by Opposer), for feasibility purposes; [redacted]

Opposer's announcement of its CLIA-certified lab is also irrelevant because Opposer's earliest *evidence* of this announcement is dated November 18, 2008 – one day *after* Meridian's November 17, 2008 priority date attributable to its ILLUMIGENE application. Opposer's Notice of Reliance, Ex. 11. But even this evidence falls well short of proving that the announcement had an impact on the perception of the relevant consumer. Opposer's CLIA-lab plans were disclosed again in January 2009 in the same release where Opposer announced its plans to enter the molecular diagnostic space. Meridian's Notice of Reliance, Ex. 4. This announcement confirms that the CLIA-lab was not yet open, as Opposer had not yet applied for CLIA-certification at the

time of publication. *Id.* Accordingly, Opposer could not have been running CLIA-certified clinical diagnostic tests even as early as January, 2009. This is yet another example of Opposer's revisionist history and empty assertions of idealized "plans."

With respect to Dr. Young's testimony, he first indicates that he believed Opposer to be "primarily focused on analysis involving human genetics" in 2008. Steven A. Young Dep. Tr., TTABVUE #96, at 18:18-24. He subsequently allowed that he "hoped" Opposer would transition to the clinical diagnostic space around the same time. *Id.* at 20:4-21. However, "hoping" for a transition does not equate to understanding that a transition was taking place or was imminent. Notably, Dr. Young confirmed that as of 2012, Next Generation Sequencing (NGS), a field in which Opposer operates, "had moved far enough along that [it] would be and will be a primary tool for the diagnosis and prognosis for cancer." *Id.* at 24:3-10. To be clear, Dr. Young's testimony is that *in 2012*, NGS had evolved to the point where it would be, at some point in the future, a tool for cancer diagnosis. Dr. Young did not offer an opinion as to whether NGS technology had evolved to that point in November of 2008.

All of Opposer's "zone of expansion" arguments fail, and Opposer has failed to prove that the relevant consumer would have believed Opposer was expanding into the clinical diagnostic field in November of 2008. At that time, Opposer was in the research market making RUO products. Opposer made no IVD products at that time. Elagin Dec. ¶ 27; Kozak Dec. ¶ 27. Opposer was always recognized as a "human genetic sequencing" company. The record wholly supports this premise, and Opposer contradicts its own CEO in an effort to argue otherwise. Accordingly, Opposer has not demonstrated that the clinical diagnostic market was within its natural zone of expansion on November 17, 2008.

(D) <u>The Similarity of Trade Channels is Not Determinative in this Case.</u>

Opposer argues that the one area where the parties' products definitely overlap is in the LDT context. Meridian dispensed with this argument in Section II(B), *supra*. Opposer also argues that because the parties may market and sell their products to the same hospitals and reference laboratories, it generally sells into the same channels of trade as Meridian. However, this is not the case given the well-recognized differences between groups of purchasers within a large hospital or a clinical laboratory. Kozak Dec. ¶ 7-15. Specifically, both a hospital and a clinical laboratory are divided into a number of different departments specializing in different disciplines. Young Dep. Tr., at 9. Each department has its own director which makes purchasing decisions for his department. Meridian's channel of trade is the Microbiology or Infectious Disease department within these larger institutions, and it interacts with the Clinical Director. Conversely, Opposer's channel of trade is the research arm within these larger institutions, and it interacts with the Research Director. Kozak Dec. ¶ 11-13; Young Dep. Tr., at 11:6-12:7. This internal channel delineation within a large medical institution has been recognized by the federal courts. In *Astra Pharmaceutical*, both parties sold products to large hospitals. In finding no infringement, the First Circuit held that use in the same, broad field "is not sufficient to demonstrate…likelihood of confusion," particularly because "the hospital community is not a homogenous whole, but is composed of separate departments with diverse purchasing requirements which, in effect, *constitute different markets* for the parties respective products." *Astra Pharmaceutical Products, Inc. v. Beckman Instruments, Inc.*, 220 USPQ 786, 791 (1st Cir. 1983) (emphasis added).

The mere purchase of goods and services "by the same institution does not, by itself, establish similarity of trade channels or overlap of customers." *Electronic Design & Sales, Inc. v.*

Electronic Data Sys. Corp., 21 U.S.P.Q.2d 1388, 1392 (Fed. Cir. 1992). This internal channel delineation is reflected in the record of this case. Specifically in the LDT context, the relevant channel of trade is the specific CLIA-certified lab existing within a larger institution. While both parties may offer their respective products to this *institution*, only ILLUMINA branded products are sold into the CLIA-certified *lab* because only RUO products are used to build LDTs in that environment. Conversely, the ILLUMIGENE products, which are IVD products, are not sold into this sub-channel because the CLIA-lab has *no use for IVD products*. As a result, it is inaccurate for Opposer to argue that there is an overlap of trade channels where LDTs are considered. Kozak Dec. ¶ 21-22.

Finally, Opposer weakly argues that the trade channels in this case must overlap because the parties have attended the same trade shows and advertised in the same publications. But the overlap is quite small compared to the overall market, consisting of only a handful of trade shows and publications whose membership and readership are sufficiently broad to cover products and consumers in both the genetic research and clinical diagnostic spaces. Opposer has failed to provide any context that would prove that a few shows and publications is significant within the overall markets. In contrast, Meridian has provided direct testimony about the disparate consumers and interests among the various hospital departments from people with personal knowledge of the organization of the relevant hospital consumers Kozak Dec. ¶4-11. Opposer cannot and has not disproved the typical barriers between the parties' markets; it only points to outliers with absolutely no quantifiable evidence of its market presence or statistical significance. Even assuming *arguendo* that Opposer's evidence reflects overlap in marketing channels, it actually proves *no* likelihood of confusion – if the parties' marketing and advertising have truly coexisted in a meaningful way for 6 ½ years as Opposer

contends, it is highly probative that not a single instance of confusion has been reported during that time. *See,* Section II(I), infra.

(E) The Consumers of the Parties' Products are Sophisticated, Discerning Purchasers Who Exercise Great Care in Making Purchasing Decisions.

The more care taken in making a purchasing decision, the less likely a consumer is to be confused because he will deliberate in his product selection and therefore differentiate between trademarks. *In re Majestic Distilling Co., Inc.*, 315 F.3d 1311, 65 U.S.P.Q.2d 1201 (Fed. Cir. 2003). If the product is one that requires careful study and negotiation, the likelihood of confusion is decreased. *Electronic Design & Sales.*, 21 U.S.P.Q.2d 1388. Also, the level of care a consumer employs in examining goods and services is generally higher for more expensive and more considered purchases. *Standard Knitting Ltd. v. Toyota Jidosha Kabushiki Kaisha*, 2006 TTAB LEXIS 9 at *55 (T.T.A.B. 2006). Finally, sophisticated purchasers, those with special training or education, are generally thought to employ a higher degree of care and are more able to distinguish between trademarks. *Electronic Design & Sales*,, 21 U.S.P.Q.2d 1388; *In re Phoenix Intangibles Holding Co.*, 2002 TTAB LEXIS 131 at *4 (T.T.A.B. 2002).

The parties do not dispute the extremely high level of sophistication and education of the relevant consumers in this case. The primary consumer of Meridian's product is the Clinical Director of a clinical laboratory. Kozak Dec. ¶ 35. That individual typically has a Masters degree or Ph.D. *Id.* The primary consumer of Opposer's products will typically have at least a bachelor's degree in a scientific field and training in molecular research and will often have doctorate level scientific degrees. Kozak Dec. ¶ 34, 42. Opposer admits that its consumers will often have both MD and Ph.D. degrees. Possemato Dep. Tr., at 73:18 – 74:21. Opposer's marketing employee, Ms. O'Grady, testified that the stakeholders in a purchasing decision in an infectious disease lab can include the lab director, the hospital administration, or both. Dec. 4,

2014 O'Grady Dep. Tr., at 127:5-128:8; May 12, 2015 O'Grady Dep. Tr., at 227:21-228:17. She admitted that the lab director would have a Ph.D. or an M.D., and that the purchaser within the hospital administration would be someone with at least an undergraduate degree, and sometimes an M.B.A. May 12, 2015 O'Grady Dep. Tr., at 228:18-22 and 229:16-14. The hospital administrator involved in such a purchasing decision is either a professional within a purchasing department whose job duties are specifically to purchase products and enter into contracts with suppliers, or a top-level executive who would have even more responsibility and education. *Id.* at 230:15-231:14; Dec. 4, 2014 O'Grady Dep. Tr., at 127:5-128:8.

Because Meridian's products are used for patient care, the clinical laboratory personnel responsible for selecting and purchasing these products exercise careful consideration in making purchasing decisions. Indeed, the Clinical Director, and the purchasing agents working with him, are required by their job duties to exercise a high degree of care when purchasing products for use in their labs because the health of the patient hangs in the balance. Young Dep. Tr., at 13:22-14:6. "Given the consequences of using the wrong product by casually focusing on only part of a product name, consumers of medical products are attentive to the need to take in and consider the entirety of the product names." Kozak Dec. ¶ 47. At least a dozen different factors are considered when a new product is examined for purchase, including without limitation the product's price, specificity, type of media used, turnaround times for results, how the product impacts the lab's existing workflow, etc. Extensive negotiations regarding pricing and supply are conducted over multiple meetings and phone calls between the prospective purchaser and the supplier of a product in advance of a purchasing decision being made. Kozak Dec. ¶¶ 32-41; May 15, 2015 O'Grady Dep. Tr., at 78:21-82:1 (describing Opposer's consumer's decision-making as a "buyer's journey" involving six stages prior to the sale: awareness of a

need, understanding a problem, a proposed solution, considering alternatives, choosing a solution, and negotiation); Young Dep. Tr., at 27:22-28:7 (explaining the factors considered in TriCore ultimately deciding not to use Meridian's products). As a result, "it would be absurd to even suggest that the Lab Director would look no further than the name(s) appearing on the product and conclude, on that basis, that one product is similar to, related to, compatible with, or a substitute for, another." Kozak Dec. ¶ 41.

Anecdotally, Opposer's evidence includes a Veracode Launch Package document from [redacted] which includes a 9-page listing of the various "Veracode Universal Capture Bead Sets" available for purchase at launch. As Ms. O'Grady testified, these "Bead Sets" differ from one another in their product descriptions only in their 20-24 letter strings of nucleic acids – A, C, G, and T. Each 20-24 letter string represents a different oligonucleotide that could have been used with Opposer's Veracode platform depending on the DNA or RNA sequence a user was trying to study. Accordingly, a purchaser ordering one of these "Bead Sets" had to differentiate among 9 pages of subtly-different strings of the letters A, C, G, and T to determine which was the correct one to purchase – a task that obviously required careful inspection. In fact, so complicated was the purchasing process relating to Opposer's Veracode instrument that Opposer not only offered its customers onsite training on the complexities of its equipment, but it also offered a dedicated sales representative and a field-application scientist *to assist with the purchasing process*. Dec. 4, 2015 O'Grady Dep. Tr., at 107:3-116:21.

Further, and although Meridian's ILLUMIGENE products are – comparatively speaking – relatively inexpensive and easy to use for a clinical diagnostic test[15], Opposer's products certainly are not – ranging between $95,000 to more than $250,000, not including the price of

[15] Meridian's ILLUMIGENE product costs between $1,250 and $3,000 per kit of 50 tests. Its ILLUMIPRO reader, however, is included with the purchase of the kit at no additional charge. Kozak Dec. ¶ 44.

consumables. Possemato Dep. Tr., at 53:16-54:11; Dec. 4, 2014 O'Grady Dep. Tr., 24:10-25:14, 104:5-10. Because Opposer's products are so expensive, a consumer is not going to thoughtlessly choose to purchase one based solely on the name of the product. "There is always less likelihood of confusion where goods are expensive and purchased and used by highly specialized individuals after careful consideration." *Astra Pharmaceutical,* 220 USPQ 786 (1st Cir. 1983). Further, "where the relevant buyer class is composed solely of professional, or commercial purchasers, it is reasonable to set a higher standard of care than exists for ordinary consumers. Many cases state that where the relevant buyer class is composed of such buyers familiar with the field, they are sophisticated enough not to be confused by trademarks that are closely similar." 3 McCarthy on Trademarks and Unfair Competition, § 23:101. [16]

In fact, it has long been recognized that purchasers of medical equipment, whether they are hospital personnel or doctors, are highly sophisticated and therefore more likely to be able to discern differences between trademarks and goods that the average consumer would overlook. *See, In re N.A.D.*, 224 USPQ 969 (Fed. Cir. 1985); *Pfizer Inc. v. Astra Pharmaceutical Products Inc.*, 33 USPQ2d 1545 (SDNY 1994) (the District court stating that as consumers, doctors are "as sophisticated a group as one could imagine"). In summary, the parties' products here are purchased by highly knowledgeable, discriminating, and sophisticated purchasers whose job duties require them to take great care in making purchasing decisions. "Sophistication is important and often dispositive because '[s]ophisticated consumers may be expected to exercise greater care.'" *Electronic Design & Sales Inc.,* at 1392. Given the level of care required of the

[16] On this issue, Opposer merely argues that sophisticated medical device consumers "are not immune to confusion," citing to the Board's non-precedential decision in *In re TM Bioscience Corp.* Opposer's Brief, p. 43. In *TM Bioscience Corp.*, the marks at issue were substantially identical, and the Board found a likelihood of confusion between products sold to research labs and clinical genetics labs. Of course, *TM Bioscience Corp.* was an *ex parte* decision without the benefit of a fully developed evidentiary records. Here, there is a wealth of evidence on this issue, and Opposer has offered *no evidence* to support its position.

relevant purchasers and the fact that the marks at issue are notably different and used differently in the marketplace, it is highly unlikely that any consumer would be confused. Accordingly, this factor favors Meridian.

(F) Opposer's ILLUMINA Mark is Not Famous for Section 2(d) Purposes.

In general, a prior mark's strength is composed of two elements: 1) the conceptual strength of the mark (distinctiveness) and 2) the commercial strength of the mark (fame). *Coach/Braunsdorf Affinity, Inc. v. 12 Interactive*, LLC, 110 U.S.P.Q.2d 1458, 1478 (T.T.A.B. 2014). Fame for Section 2(d) purposes is to be measured with regard to "the class of customers and potential customers of a product or service, and not the general public." *Palm Bay Imports, Inc. v. Veuve Clicquot Ponsardin Maison Fondee en 1772*, 73 U.S.P.Q.2d 1689 (Fed. Cir. 2005). It is the duty of the party asserting that its mark is famous to "clearly prove it." *See, Morgan Creek Productions, Inc. v. Foria International, Inc.*, 91 USPQ2d 1134 (TTAB 2009). Typical evidence of fame includes: (1) sales of products bearing the mark; (2) the amount of money spent on advertising products bearing the mark; and (3) customer brand awareness. *See generally, Bose Corp. v. QSC Audio Products, Inc.*, 63 USPQ2d 1303 (Fed.Cir. 2002). However, "the renown of opposer's marks outside the United States or exposure of the foreign public to opposer's marks is irrelevant." *Hard Rock Café Licensing Corporation v. Elsea*, 48 U.S.P.Q.2d 1400, 1405 (T.T.A.B. 1998). Further, the Federal Circuit has cautioned that "raw numbers of product sales and advertising expenses…in today's world may be misleading." There must be "some context in which to place raw statistics," such as providing data on the percentage of the industry total these expenditures represent. *See, Bose Corp.*, 63 USPQ2d at 1309.

The conceptual strength of Opposer's ILLUMINA mark is treated in Section II(G), *infra*, and there Meridian demonstrates that ILLUMINA cannot be deemed inherently strong due to

the widespread registration and use of similar marks by third parties in the scientific and medical fields. As to commercial strength, Opposer's purported evidence that ILLUMINA is a famous mark is found on pages 23 and 24 of its brief (and in the documents referenced therein) and consists solely of the following: (1) Illumina is a publicly traded company with a market cap of around $25 billion; (2) its sales have grown from $366 million in 2007 to over $1 billion in 2013; (3) it has been listed on Forbes' list of fastest growing technology companies in America four times between 2006 and 2010; and (4) it has spent over $19 million in advertising (including on "agency fees") between 2008 and 2013, with [redacted] of this ad spend "targeted" to diagnostic customers. Not only does this evidence fall well below what the Board has historically required to demonstrate fame in the 2(d) context in an *inter partes* proceeding, but it grossly overstates the relevant information.

With respect to its first piece of evidence, the mere fact that Illumina, Inc. is a publicly traded company with a given market capitalization does not speak to the strength or renown of the ILLUMINA mark. Rather, and at most, this evidence relates only to the company name, "Illumina, Inc.," as Opposer provides no basis by which to tie this evidence to consumer recognition of its ILLUMINA *trademark*. With respect to its asserted sales figures, it should first be noted that "revenue" does not correlate dollar-for-dollar with actual sales of products and/or services, as sales are just one component of revenue (which includes non-trademark items such as interest income, technology licensing revenue, etc.). Indeed, Opposer provides no evidence whatsoever of the number or volume of products or services it has sold, and whether those products or services have been offered under the ILLUMINA mark save the broad

allegation that the ILLUMINA house mark "appears on everything." [17] Further, in its 2007 Annual Report, Opposer stated that "during 2007, $159.1 million or 43% of our total revenue came from shipments to customers outside the United States." Meridian's Notice of Reliance, Ex. 2(e), ILLUM-2319. Further, in its 2008 Annual Report, Opposer stated that "shipments to customers outside the United States totaled $293.2 million, or 51% of our total revenue during 2008." Meridian's Notice of Reliance Ex. 2(f), ILLUM-2412. This trend continued all the way through 2013, where in its Annual Report, Opposer stated that, "shipments to customers outside the United States totaled $706.5 million, or 50% of our total revenue, during fiscal 2013."Because non-U.S. sales revenue is irrelevant in the context of a Board proceeding, the Board must deduct roughly half of Opposer's asserted revenue (i.e., not "sales") figures before even considering whether they are sufficient to demonstrate fame.

As to the evidence relating to the Forbes, list, Opposer has not cited to any precedent which stands for the proposition that being listed among "fast growing companies" somehow equates to being well known and famous. Indeed, Opposer doesn't even argue the point; it merely submits this evidence to be taken on its face. Further, the Forbes listing includes "technology companies" generally, which includes industries as disparate as software, internet services, semiconductors, pharmaceuticals, telecommunication, motion picture audio, and security systems. Possemato Dec. Ex. 229, ILLUM-0925 – 0926. Opposer cannot possibly be asserting that its mark is famous in these other industries, and therefore the Forbes evidence is

[17] Although Opposer contends that "all" of its products bear the ILLUMINA mark, it has not substantiated that claim, and there are several admitted exceptions in the record. Ms. Possemato admitted that Opposer has partnered with other businesses and has acquired several companies, and each time this occurs, there are "transitional periods" with respect to the branding of the related products and services. Possemato Dep. Tr. at 109:11-110:6. One example was the "Verifi Prenatal Test," offered by "Verinata Health." *Id.* at 79:5-80:21. The Verifi service kept its brand name post-acquisition. *Id.* If Opposer at some point added the ILLUMINA mark to the Verifi product or marketing materials, the timing and sales volume before and after the transition is not in the record. The same is true of all other products and services that were added by partnership or acquisition.

wholly unrelated to "the class of customers and potential customers of [Opposer's] product or service" pertinent to the 2(d) fame analysis.

With respect to Opposer's advertising evidence, Opposer has utterly failed to prove how much of its advertising was directed to the clinical diagnostic space in any given year. Opposer broadly asserts that [redacted] of its total marketing expenses from "January 2008 through December 31, 2013" were "targeted to clinical diagnostic customers." Possemato Dec. ¶ 44. But Opposer fails to identify what this percentage was in any given year. From this pseudo-statistic, it is plausible (indeed, likely given the date range provided) that little to no money was spent in the clinical diagnostic space from 2008 to 2010 when its Diagnostics Business Unit was in its infancy, and that a large percentage was spent from 2011 to 2013, when Opposer finally offered an FDA-cleared, IVD product or two, *adding up* to [redacted] of the total. In this case, where November 17, 2008 is the critical date, Opposer's vague assertion amounts to zero evidence of expenditure in the clinical diagnostic space *at the relevant time*.

Moreover, even if Opposer is given the benefit of assuming the percentages remained stable year-to-year (an inference to which Opposer is not entitled at this stage), Opposer has only spent approximately [redacted] per year "advertising" its diagnostic products and services between 2008 and 2013. This figure includes, per Opposer's admission, "agency fees," and the record is silent as to how fees paid to an advertising agency impact consumer recognition. Assuming, as is the case with Opposer's sales, that roughly half of the advertising figures can properly be credited to advertising within the U.S. (which can only be a guess because Opposer has introduced no evidence into the record on this point), Opposer spends only around [redacted] per year advertising its "diagnostic products" in the United States. However, this figure should probably be reduced further, if considered at all, because in its 2008 Annual

Report, Opposer concedes that, "during 2008, we had limited activity related to the Diagnostics Business Unit and operating results were reported on an aggregate basis…accordingly, we operated in one reportable segment during 2008." Meridian's Notice of Reliance Ex. 2(f), ILLUM-2412. Even in its 2013 Annual Report, the situation is unchanged, as Opposer publicly stated that "during all periods presented, the Diagnostics operating segment was *immaterial* to the financial statements as a whole. Accordingly, the financial results for both operating segments have been reported on an aggregate basis as one reportable segment" (emphasis added).[18] Opposer's assertion that it materially operated in the clinical diagnostic market during these years is therefore dubious according to its own Annual Reports, and its claim to have achieved "fame" through advertising and sales in that market is completely unsupported.

Nowhere in the record does Opposer even suggest that some, most, or all of its revenue or advertising expenditures is tied to its ILLUMINA mark. Opposer has produced no evidence demonstrating that consumers who purchase its products do so because of the mark attached thereto or for some other reason, or that consumers even notice the ILLUMINA house mark when the products are otherwise prominently branded with and referenced by their own, separate product brands. Further, Opposer has produced no evidence demonstrating that its advertising is directed toward promoting a specific mark or, instead, the utilitarian advantages of its products. Indeed, Opposer admitted in its Summary Judgment Brief that some of its advertising "specifically promote[s] [its] emerging diagnostic business" generally, and not any particular trademark specifically. TTABVUE #37. Opposer has not shown what its competitors' sales have been or what its competitors spend on advertising as a point of comparison. In a vacuum, Opposer's numbers are meaningless.

[18] *See,* https://www.illumina.com/content/dam/illumina-marketing/documents/company/investor-relations/IlluminaInc-2013-10K.pdf

Opposer has claimed that it was "dominating the sequencing market" in 2009 Possemato Dec. Ex. 229; ILLUM-0929, and that it "ha[d] captured as much as 70% market share in certain fields of genetic analysis" as of January, 2009. *Id.*, ILLUM-0930. This claim, however, only supports Meridian's position that Opposer is (and has historically been known as) a genetic sequencing company – not a clinical diagnostic company. Even now, Opposer appears not to have crossed over into the clinical diagnostic space as a legitimate participant, and certainly not at a level where one could argue that its mark is famous in this space. *See,* Section II(B), *supra*. The Board, therefore is cautioned to view Opposer's unsubstantiated arguments with a health dose of skepticism. One concrete fact, as opposed to Opposer's puffery, is that Opposer's only products ever cleared by the FDA for in vitro diagnostic use in a clinical setting were: (1) the VeraCode Factor V/II product in April of 2010 which has since been discontinued; and (2) its MiSeqDx Cystic Fibrosis System in November of 2013 - 3 ½ years after Opposer initiated these proceedings. Heath Dec. ¶ 25.

Based on *this record*, the Board cannot conclude that Opposer's ILLUMINA mark is well known or famous for 2(d) purposes in *any* market, and most certainly not in the clinical diagnostic space. Accordingly, this factor does not favor either party.

(G) Widespread Third-Party Registration and Use of ILLUM- and LUMI-Formative Marks Demonstrate that Such Marks are Weak.

If the evidence establishes that the consuming public is exposed to third-party use of similar marks on similar goods, this evidence "is relevant to show that a mark is relatively weak and entitled to only a narrow scope of protection." *Palm Bay,* at 1693. Third-party registrations are relevant to show that a portion of the mark is so commonly used that the public will look to other elements to distinguish the source of the goods or services *See, AMF Inc. v. American Leisure Products, Inc.*, 177 USPQ 268, 269-70 (C.C.P.A. 1973). By introducing this evidence, the

party is showing that customers have become so conditioned by the other similar marks that the consuming public can distinguish between such marks using only minute distinctions. *Palm Bay*, 73 U.S.Q.P.2d at 1694. In general, evidence of this type will establish consumer awareness and recognition of similar marks on similar goods. *Id.*

As Opposer points out, it uses its ILLUMINA mark so that that the leading "I" is printed in a different color. This light orange shade de-emphasizes the "I" from the remaining letters in the mark which are printed much darker:

illumina®

Because the Board will consider the standard character mark as actually used, and because Opposer's use makes the "I" in ILLUMINA almost disappear, third party use of both ILLUMI- and LUMI-formative marks are relevant in this context.

Meridian has made of record status copies of third-party registrations which contain the "ILLUMI-" and "LUMI-" prefixes along with verified evidence showing that all of these marks were in use as of January, 2015. Meridian's Notice of Reliance, TTABVUE #76-77, Exs. 12, 13. All of the registrations recite goods and services in the scientific and medical fields. Not counting Opposer and Meridian, twelve (12) unique entities own registrations for ILLUMI- marks in these fields. Not counting Opposer and Meridian, twenty-five (25) unique entities own registrations for LUMI-marks in these fields, including, most relevantly, Luminex Corporation (identified by Opposer as one of its competitor in Opposer's Annual Reports as far back as 2003 and in Opposer's documents), who owns a registration for LUMINEX. See, e.g., Possemato Dec. Ex. 216.[19] The existence of these registrations demonstrates that both the "ILLUMI-" and

[19] Should Opposer argue that some portion of this coexistence is irrelevant because the goods/services recited in the coexisting registrations are unrelated to the goods/services at issue here, Meridian notes Opposer successfully

"LUMI-" prefixes (which mean "light") are commonly used in the scientific and medical fields. As a result, when a consumer encounters a mark that contains one of these two prefixes, he will look to the other elements or aspects of the mark because he will not attribute any source-identifying qualities to the commonly-used prefixes. Accordingly, this factor favors Meridian.

(H) Opposer Does Not Own a Family of Marks Denoted by the "ILLUMI-" Prefix.

If a business uses a group of trademarks that have a single component in common, third party use of a mark which also shares that component may be forbidden if the public believes it to be one of a "family" of marks emanating from a single source. *J & J Snack Foods Corp. v. McDonald's Corp.*, 18 U.S.P.Q.2d 1889 (Fed. Cir. 1991); *Eleven, Inc. v. Wechsler*, 83 U.S.P.Q.2d 1715 (T.T.A.B. 2007). To prove the existence of a "family" of marks, a plaintiff must prove that: (1) prior to the junior user's entry, all or many of the marks in the alleged family were used and promoted together in such a way as to create public perception of the family "surname" as an indication of source; and (2) the family "surname" is distinctive. *Truescents LLC v. Ride Skin Care, LLC*, 81 USPQ2d 1334 (TTAB 2006). Whether a "family" of marks exists is a question of fact. In order to own a family of marks, the proponent must have used joint advertising and promotion of the family in a manner designed to create an association of common origin for all marks containing the distinguishing family element. *AM General Corp. v. DaimlerChrysler Corp.*, 65 USPQ2d 1001 (7th Cir. 2002). Merely using or registering a series of marks with a common prefix does not, without more, prove that a "family" of marks exists. *J & J Snack Foods* at 1462.

First, Opposer has failed to demonstrate it was using more than one ILLUMI-formative mark before Meridian's November 17, 2008 priority date. In fact, the opposite is true. Based on

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opposed **ILLUMISCULPT** for *"medical apparatus and instruments for use in surgery…medical clinic providing weight loss solutions, services and programs, nutrition counseling…(etc.)"* in Opposition No. 91219208 and **ILLUMINA 3D** for *"computer software for implantable neurostimulation systems"* in Opposition No. 91211615. Because Opposer's own enforcement activity suggests it believes goods/services as disparate as these are relevant to the scope of protection of its ILLUMINA mark, coexistence of similar marks must be considered by the Board in this case.

the record, the only mark Opposer was using as of November 17, 2008 was ILLUMINA. The ILLUMINADX mark had not been applied for until May 28, 2009 or used until March 19, 2010.

Further, the evidence pertaining to "Illumicode" dates to 2010 at the earliest. Opposer asserts that it continuously used the "Illumicode" mark since August 2002. Opposer's Brief, p. 11. Its only support for this assertion is paragraph 40 of the Possemato Declaration, which itself refers to Exhibit 214. Exhibit 214 consists of four documents. The first references the word "illumiCodes" 4 times in text with no use of the "TM" symbol.[20] ILLUM-0856 – 0858. Moreover, Ms. Possemato admitted that the "oligos" referred to as "Illumicodes" were an internal part of a now-defunct "BeadArray" technology and were never marketed or sold separately. *Id.* at 103:10-18. The document includes a copyright date of 2010 and includes the legend, "FOR RESEARCH USE ONLY." The second document is a two-page printout from a website dated April 2012. No reference to "Illumicode" is apparent. ILLUM-0859 – 0860. The third document is also undated, ILLUM-0861, and on cross-examination, Ms. Possemato had no idea when this document was created. Possemato Dep. Tr., at 102:13-103:1. The identity of the fourth document is also unclear, it is also undated, and here the word "IllumiCode" appears just once. Ms. Possemato could neither identify this document nor speculate as to its date of creation. *Id.* Given the foregoing is the sum-total of Opposer's evidence of its continuous use of its purported "Illumicode" mark, Opposer has fallen well short of proving it should be interpreted as a common law trademark.

In addition, the record pertaining to "Illuminotes" shows use of that term only in 2011. Opposer asserts it continuously used the "Illuminotes" mark since April 2006. Opposer's Brief, p. 11. Its only support for this assertion is paragraph 41 of the Possemato Declaration, which

[20] Opposer used "TM" with other marks in which it was claiming trademark rights in this document.

itself refers to Exhibit 215. Exhibit 215 consists of five "issues" of Opposer's "Illuminotes" newsletter dated April, June, August, September, and November of 2011. ILLUM-0864 – 0880. The next document is a screen capture of an excerpt of an "Illuminotes" newsletter dated April 2014. The last two pages of Exhibit 215 appear to be a screen capture of an email in which an issue of the "Illuminotes" newsletter is imbedded.[21] The addressee field of this email has been redacted, and the email originates from "Community." It appears to be dated April 20, 2006, but there is no proof this email was actually sent, and Ms. Possemato did not testify to knowing whether it was. Opposer does not outwardly claim the term "Illuminotes" as a trademark anywhere in Exhibit 215, and in this sense, Opposer's seems to be trying to "create" a trademark after the fact for the benefit of this case where one never existed in the first place. Further, there is a full 5 year gap (April 2006 to April 2011) between these so-called "representative" uses of the term "Illuminotes"[22]. Given the foregoing is the sum-total of Opposer's evidence of its use of its purported "Illuminotes" mark, Opposer has again fallen well short of proving this term should be interpreted as a common law trademark.

Second, the record demonstrates that Opposer has not advertised or promoted its marks as a family. No more than two (2) of Opposer's alleged "family" members has ever been used together. The record shows use of "Illuminotes" with ILLUMINA (ILLUM-0864 – 0880), use of "Illumicodes" with ILLUMINA (ILLUM-0856 – 0863), and use of ILLUMINADX with ILLUMINA. Such fragmented use does not constitute use of "all" or "many" of the family members together. Moreover, adding ILLUMINA in the header or the footer of each marketing piece does not establish that the "family" members have been marketed such that consumers will recognize "ILLUMI-" as the "family" "surname."

[21] Neither of these documents is Bates numbered, and neither was produced by Opposer during discovery.
[22] Nonuse for 3 consecutive years is *prima facie* evidence of abandonment. 15 U.S.C. § 1127.

Even assuming Opposer has properly used a "family" of marks, a surname may be so non-distinctive that it may be incapable of earning strong family significance. *Creamette Co. v. Merlino*, 132 USPQ 381 (9th Cir. 1962). As Meridian has demonstrated in Section II(G), supra, the prefixes "ILLUMI-" and "LUMI-" are commonly used in the medical field, and as a result, "ILLUMI-" is not distinctive enough to function as the family component.

(I) Despite Having Coexisted in the Marketplace for More Than 6 ½ Years, Neither Party Reports Any Instances of Actual Confusion.

Where products or services have co-existed in the marketplace for an extended period of time with no actual confusion, the factor weighs against a finding of likelihood of confusion. *Citigroup Inc. v. Capital City Bank Group, Inc.*, 94 U.S.P.Q.2d 1645, 1662 (T.T.A.B. 2010), aff'd, 98 U.S.P.Q.2d 1253 (Fed.Cir. 2011); *see also, CareFirst of Maryland, Inc. v. First Care, P.C.*, 77 U.S.P.Q.2d 1577 (4th Cir. 2006) (no likelihood of confusion where marks had coexisted for 9 years); *Brookfield Communications, Inc. v. West Coast Entertainment Corp.*, 50 U.S.Q.Q.2d 1545 (9th Cir. 1999) (no likelihood of confusion where marks had coexisted for 5 years).

Meridian engaged in pre-FDA clearance testing and prototype marketing for its ILLUMIGENE and ILLUMIPRO branded products beginning in December of 2008. Kozak Dec. ¶ 54. Such testing and prototype marketing has been held by the Board to constitute bona fide use of a mark. *Automedx, Inc. v. Artivent Corporation*, Opposition No. 91182429 (not reported in USPQ) (TTAB 2010). Further, Meridian began advertising and promoting its ILLUMIGENE and ILLUMIPRO products at trade shows in April and May of 2009. Kozak Dec. ¶ 55. Therefore, Meridian's marks have coexisted with the ILLUMINA mark for more than 6 ½ years. Opposer has failed to identify or even allege a single instance of actual confusion during this time despite Opposer's position that the relevant consumers are the same, the channels of trade are the same, the parties appear at the same trade shows together, and the products are used for the same

purposes.[23] Specifically, in its interrogatory responses, Opposer first attempted to evade the issue, and then admitted that it had "not yet documented any instances of confusion". Meridian's Notice of Reliance, Ex. 1. Similarly, Meridian is aware of no instances of confusion despite its advertising having reached "almost 100% of the possible accounts in the marketplace." Kozak Dec. ¶ 54 – 58. The absence of actual confusion – in a scenario which, if Opposer is to be believed, provided ample opportunity for confusion to occur – is yet another fact that weighs against a finding of likelihood of confusion, especially considering the length of time the parties' marks have coexisted.[24] As a result, this factor weighs in favor of Meridian.

(J) Because Opposer's ILLUMINA Mark is Used as a House Mark and Meridian's Marks Are Used as Product Brands, Confusion is Less Likely.

The fact that ILLUMINA is a house mark and ILLUMIGENE / ILLUMIPRO are product brands renders confusion even less likely. In testimony that has not been challenged by Opposer, Mr. Kozak described the buying process for products in the clinical diagnostic lab. Kozak Dec. ¶¶ 9-14. During this process, the consumer is first exposed to the company as a potential (or existing) vendor, and then exposed to that company's products. So, in this case, the consumer will first interact with Meridian, and will then learn that it offers a number of different products, including the ILLUMIGENE product. Similarly, the consumer will first interact with Illumina, and will then learn that it offers products such as BEADXPRESS.

When the parties' marks are viewed at these different levels, as consumers would encounter them in the marketplace, the differences are unmistakable. At all times, the consumer

[23] Opposer attempts to argue that the GenomeWeb search engine was "confused" when it returned the query "Did you mean: illumina" when Opposer ran a search for the term "Illumigene" on November 5, 2014. Opposer's Brief, p. 26. However, Opposer admits to not knowing how GenomeWeb's search algorithm works, Possemato Dep. Tr., at 76, and it ignores the fact that every article identified in the search referred to Meridian or its ILLUMIGENE products, and this anecdote is therefore evidence of nothing.

[24] Indeed, Dr. Steven A. Young, Scientific Director of Infectious Disease at TriCore Reference Laboratories – an individual identified by Ms. O'Grady in her Rebuttal Declaration as an individual who "performs infectious disease diagnostics along with other areas of diagnostics…related to genetic health" – testified that he would not be confused by the parties respective trademarks. Young Dep. Tr., at 15:10-11.

understands he is dealing with Meridian on the one hand or Illumina on the other during the initial point of contact. Kozak Dec. ¶ 40. As a result, "it is the *company's* brand that is foremost in the consumer's mind – not the names of the products that the company offers to meet a particular need." *Id.* Thereafter, when a product is requested and purchased from one of the companies, the consumer "focus[es] on and use[es] the name of the supplier of the product *as well as* the full name of the product itself" (emphasis added). Kozak Dec. ¶ 48. Ms. Possemato also acknowledges the role "positioning" of a party's trademarks plays in eliminating confusion in the relevant space, as she explained this "positioning" is what has prevented ILLUMINA from being confused with LUMINEX even though both terms are used as house marks. Possemato Dep. Tr., at 96:15-98:3. Accordingly, this factor also favors Meridian.

(K) Coexistence of the Parties' TRU-formative Marks Proves that Confusion is Unlikely in this Analogous Case.

The Board considers the coexistence of third party registrations for similar marks without actual confusion as evidence that confusion is unlikely. *In re Strategic Partners, Inc.*, 102 U.S.P.Q.2d 1397, 1399 (T.T.A.B. 2012). Here, the parties themselves already own and use marks with the shared prefix, "TRU-", without any reported instances of actual confusion. Opposer owns registrations for TRUSEQ and TRUSIGHT, and an application for TRUGENOME. Meridian owns registrations for TRU BLOCK, TRU EBV-G, TRU EBV-M, TRU FLU, TRU HSV 1 AND 2 IGG, TRU LEGIONELLA, and TRU RSV. TSDR printouts of these registrations and verified evidence demonstrating these marks are currently in use have been made of record. Meridian's Notice of Reliance, Ex. 14.

With the exception of TRU BLOCK, all of Meridian's TRU-formative marks are registered for diagnostic tests similar to its ILLUMIGENE products. Meridian's recitations make clear that its goods are used for "disease testing and treatment" (synonymous with "qualitative

diagnosis"). Similarly, the recitations of Opposer's TRU-formative marks closely track the recitations in its ILLUMINA marks. Moreover, Registration No. 4064847, TRUSEQ, specifically indicates that its "reagents and reagent kits" are intended for use "in the fields of scientific, diagnostic and clinical research." Meridian has priority over these TRU-formative marks, as the earliest filings on Meridian's registrations date to 2006 while Opposer's earliest filing date is mid-2010. Meridian did not challenge Opposer's TRU-formative filings (and vice versa), and Opposer applied for its TRU-formative marks with constructive knowledge of the majority of Meridian's existing marks.

It is not surprising that neither party viewed the other's TRU-formative marks as an issue, as the goods are different and the marks are different except for the shared prefix. Kozak Dec. ¶ 49-51. Indeed, Meridian's TRU-formative marks are registered in the form, "prefix + name of virus tested for." In this configuration, the only distinctive portion of Meridian's marks is the prefix, "TRU-." Similarly, Opposer's TRU-formative marks are in the form "prefix + descriptive term," and as a result, the only distinctive portion of Opposer's marks is also the prefix, "TRU-." Meridian is not aware of any instances of actual confusion between the parties' TRU-formative marks. Kozak Dec. ¶ 53. Opposer has not alleged any instances of actual confusion between these-marks despite coexisting in markets which Opposer claims are related.

Opposer has now alleged, *under nearly identical facts*, that Meridian's ILLUMIGENE and ILLUMIPRO marks are likely to be confused with ILLUMINA, simply because they share the same prefix. Opposer's contradictory position here simply does not hold water. If Opposer's position is accepted, the TRU-formative marks should be an even bigger problem for the parties, as both parties use their respective TRU-formative marks as product marks instead of at different levels as explained in Section II(J), *supra*. The parties have already demonstrated they

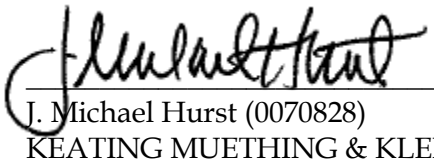
can do business under marks sharing the same prefix with descriptive suffixes without confusion occurring, in part because consumers in the relevant field are conditioned to seeing product names which share similar prefixes. Kozak Dec. ¶ 47-48. Either the markets are not as closely related as Opposer asserts or the consumers are sophisticated enough to differentiate the products based on the suffixes; or, as Meridian has demonstrated, both. This analogous evidence of the parties' coexistence is highly probative of whether there is a likelihood of confusion in this case, and this factor overwhelmingly favors Meridian.

CONCLUSION

Opposer would have the Board believe that the individuals responsible for purchasing and using the parties' respective products – individuals who are highly educated, highly experienced, and performing critical analysis bearing on the physical health of patients – will carelessly mistake one product for another simply because one party's house mark and the other party's product brand happen to share a commonly-used prefix, despite the fact that the products are used differently, employ different technologies, operate differently, and are incompatible with one another, in addition to being subject to different FDA regulations and marking requirements. Frankly, Opposer's position strains credibility, and the parties have already demonstrated they can coexist without confusion. For the foregoing reasons, Meridian respectfully requests that the Board: (1) deny Opposer's opposition and permit Serial Nos. 77/768176 and 77/775316 to proceed to Allowance, (2) deny Opposer's petition to cancel Registration Nos. 3868081 and 3887164, and (3) dismiss both actions with prejudice.

Dated this 4th day of September, 2015.

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Brief of Applicant / Registrant Meridian Bioscience, Inc. was served upon Susan M. Natland, Knobbe, Martens, Olson & Bear, LLP, 2040 Main Street, Fourteenth Floor, Irvine, California, 92614 by first class mail this 4th day of September, 2015.

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